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UNCLAS SECTION 01 OF 03 BRASILIA 002143

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E.O. 12958: N/A
TAGS: ETRD SOCI TBIO KIPR IPR
SUBJECT: STAFFDEL O'KEEFE EXAMINES PHARMACEUTICAL REGULATORY ISSUES

This cable was co-drafted by AmEmbassy Brasilia and AmConsulate Sao Paulo.

¶1. (SBU) Summary and Introduction. House Energy and Natural Resource Committee Counsel Colleen O'Keefe and Chris Knauer visited Brazil June 27 to July 2 to look at the degree to which local drug companies were producing substandard medicines - which eventually might find their way into the U.S. The two counsel, accompanied by industry reps and Embassy/Consulate staffers, met with Brazilian regulatory authorities, government officials, current and former federal deputies, scientists, victims of substandard medicines, prosecutors and pharmaceutical production facility staff. Staffdel focused in particular on a class of drugs labeled "similars," which are like generics but are not in all cases tested for bio-equivalence. Officials at ANVISA (the Brazilian version of the FDA) admitted that only by 2014 would producers of similar drugs be required to test their products, but even then the required tests would only be a fraction of what the FDA requires. The current (and former) Federal Deputies that Staffdel spoke with agreed that the situation was less than ideal, but felt that only a consensus solution (involving large and small "similars" producers, consumers, and government) would move the ball forward. They did not anticipate major changes to the prevailing regulatory system in the short-term. End Summary and Introduction.

Background

¶2. (U) In 1999, Brazilian law authorized the production of generic drugs (i.e., pharmaceuticals which copy the formulae of reference medicines). Generic products must undergo bio-equivalence tests prior to being authorized for use, and are sold under the name of the product's principal active ingredient. The 1999 law, however, did not extinguish the existence of the country's pre-1999 category of home-grown low-cost medicines, called "similars," i.e., similar to reference drugs.

¶3. (U) Similars sprouted in Brazil during the 1950s, a time when the Brazilian government did not recognize international pharmaceutical patents. Similars account for nearly 40 percent of the local pharmaceutical market and sell for up to ten percent less than the corresponding reference drug. They are sold under their own brand name, and prior to November 2003 were not required to undergo any bioequivalence tests at all. While testing requirements are gradually being phased in, only in 2014 will all similars be obliged to undergo tests prior to their sale. Of the 17,000 drugs -- and 32,000 different variations of drugs/dosages - registered with ANVISA, a large percentage fall into the category of similars. Among the firms producing similars are the 17 state-owned pharmaceutical manufacturing companies in Brazil. The Brazilian government is also a purchaser of similars as well (overall, it buys 51% of drugs sold in the country).

Ineffective Medicines

¶4. (SBU) Local Brazilian attorneys briefed staffdel on the problems caused by substandard similar medicines which may be ineffective, have no effect at all (placebo), or worse be harmful to those taking the drug. Since many similars are used for chronic conditions, a causal link is often difficult to establish. They pointed out that containing the same active ingredient does not mean the similar is as effective as the reference drug, which may have a completely different molecular structure. An illustrative example these interlocutors offered was that of carbon: diamonds and coal have the same chemical formula but that does not mean that would have the same effect on the body. They argued that bioequivalency testing is essential. However,

only a fraction of similar medicines in Brazil have been subject to bioequivalency testing and it is not possible for consumers to determine which have undergone testing and which have not.

¶5. (SBU) Yet another problem these attorneys identified was the issue of the quality of the active ingredients in similar drugs. Often the active ingredients contained in such drugs are produced in labs, perhaps in India or China, which are not subject to strict quality control standards. Indeed, a February article from Veja magazine, Brazil's equivalent of "Time," noted that Aventis Pharma was in the midst of three years of litigation in an effort to get a similar drug with unclear lineage (and competing with one of the company's own products) withdrawn from the market.

¶6. (SBU) Local attorneys introduced Staffdel to the surviving family members of two victims of an ineffective similar drug (Celobar). According to these attorneys, ANVISA had approved Celobar - which contains the active ingredient barium sulfate - but later recalled the product after it was deemed unsafe for consumption. However, notwithstanding the recall, they said, Celobar can still be purchased from many pharmacies in the country. Overall, 23 deaths have been attributed to the drug so far.

Overburdened Regulators

¶7. (SBU) In a frank and open meeting with staffdel, ANVISA drug regulator Dr. Davi Romel outlined some of the hurdles ANVISA faces in bringing order to the chaotic Brazilian pharmaceutical market. The situation involving similars, he stated, had already been dealt with legislatively and was gradually coming under control. (Comment: this was a statement with which other commentators did not agree. End Comment.) Romel said that in November 2004 the production of 30 similar drugs had been cancelled and another 100 temporarily taken off the market. He thought that the biggest problem ANVISA faces is the sheer number of local drug manufacturers, many of which are small and medium-sized firms which do not have rigorous quality control standards. While ANVISA seeks to improve industry quality through yearly inspections, he admitted that the agency lacks the FDA's decades-long regulatory tradition.

¶8. (SBU) During the past few years the number of local companies in the field had dropped from 380 to 250, he noted, adding that in the end it would need to decline even more as eventually this would be an industry in which "only the big guys could play." As the number of firms (and jobs) shrank, he continued, ANVISA faced increasing pressure to ease up on its regulatory oversight. An even bigger problem, Romel felt, was the existence of 6,000 compound-producing pharmacists, comparable to the by-gone apothecaries in the U.S., who manufactured medicines in their backrooms. These apothecary-manufactured drugs were often sold in low-cost pharmacies which cater to the poor. The conceptual problem that Brazil faced as a whole, Romel commented, was that often the issue of quality health care was equated with access to affordable medicines, with questions such as safety of medicines often taking a back seat. While ANVISA could set standards, he declared, actual enforcement of its dictates fell to state law enforcement authorities, many of which were overburdened and understaffed.

Comments from a Former Brazilian Congressman

¶9. (SBU) StaffDel also met with former Congressman Vicente Caropreso (PSDB) (please protect) from Santa Catarina state. Caropreso is a neurosurgeon and was one of the leaders in Congress that fought for the institution of generics in Brazil in the late 1990s. At June 28 dinner, he opined that the 2014 deadline for similares to meet generic standards was too distant and alleged that corruption and deal making between the similar companies and ANVISA was keeping the industry alive. When asked what should be done about similares, Caropreso said that the government should concentrate its efforts on monitoring the production, distribution and sale of all drugs. Tighter controls/standards, he felt, would naturally push out the similar producers and make room for legitimate generic drugs as a safer alternative.

Changing a Culture

¶10. (SBU) Finally, StaffDel met with members of the Brazilian Bar Association (OAB) and a professor of pharmacy from the University of Sao Paulo (USP). OAB members stated that they have launched a public awareness campaign in Santa Catarina State focusing on the distribution of pamphlets to physicians and citizens explaining the dangers of similares. In response, similar producers in Santa Catarina have accused the OAB of attacking national industry in support of

"large, exploitative multinational drug companies." Meanwhile, in staffdel's conversations with Professor Yasaka, Vice-President of the Sao Paulo Pharmaceutical Society, the latter noted that he has done extensive research on the effectiveness and safety of similar drugs -- and as a result has become one of their strongest opponents. Both Yasaka and OAB members echoed Caropreso's view that there is widespread corruption within the industry.

¶11. (U) Staffdel O'Keefe has cleared this cable.

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